



# **TENNESSEE BUREAU OF INVESTIGATION**

## *Forensic Services Division*

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### Quality Assurance Manual

#### Process Requirements-Selection and Verification of Methods

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## **7 Process Requirements**

### **7.2.1 Selection and Verification of Methods**

**7.2.1.1** Standard operating procedures (SOPs) are a key element in establishing and maintaining quality within the TBI Laboratory. Thus, it is the policy of the TBI Laboratory for each discipline to have and use written procedures for all examinations/calibrations within their scope. These procedures include, when necessary, handling, transfer, storage, and preparation of evidence to be examined. Operating instructions to equipment used for laboratory activities will be readily available. Appropriate SOPs will address estimation of the uncertainty of measurement; sampling; calculations, including any statistical techniques for the analysis of examination data; and limitations of the procedure including any quality affecting environmental conditions.

**7.2.1.1.1** Each unit will have procedures in place for evaluating the characteristics of unknown items or test data prior to comparison to a known.

**7.2.1.1.2** Breath Alcohol Calibration SOPs address the range of ethanol values used for assessing the accuracy of an instrument.

**7.2.1.1.3** Breath Alcohol Calibration SOPs address the sources of material used for calibration activities and instrument adjustments.

**7.2.1.2** Discipline supervisors/technical leaders will be responsible for maintaining their standard operating procedures and ensuring the procedures are readily available to appropriate personnel. Procedures will be periodically reviewed and adjusted as necessary to meet customer and laboratory needs.

**7.2.1.3** The TBI Laboratory uses published standard operating procedure. Current versions are available to all personnel on Ensur. The standard operating procedure will be supplemented with additional details as necessary.

**7.2.1.4** Examiners will select appropriate technical procedures to meet the needs of the submitting agency while taking into account the nature of the evidence and the facts of the case. Prior to TBI validation, these technical procedures should be published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts, or journals, as specified by the manufacturer of the equipment or developed by the TBI Laboratory.

**7.2.1.5** The TBI Laboratory will confirm that it can properly use a standard operating procedure prior to introducing it for forensic examinations or calibration activities. If the standard operating procedure changes, the confirmation will be repeated. TBI Laboratory-developed technical procedures or procedures adopted by the TBI Laboratory, including standard operating procedures, are used as appropriate.



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**7.2.1.6** All SOPs used in the TBI Laboratory will be used within their intended scope. If it becomes necessary to use a method outside the intended scope, validation procedure will be followed. Validations will be performed by personnel competent in the applicable discipline. All SOPs are reviewed and authorized by management prior to implementation.

**7.2.1.7** Each discipline will use validated technical procedures; however, this does not prevent the examiner from deviating from a procedure. Deviations from a technical procedure must be within the bounds of good laboratory practice, documented, justified, and authorized by management prior to testing/calibration. Management will track deviations and should make necessary changes to procedures to minimize the need for deviations where appropriate.

**7.2.1.8** The laboratory document control system (Ensur) allows all personnel to access up-to-date policies and procedures. It is the responsibility of all personnel to access current procedures from Ensur for all laboratory activities.